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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,366	12/22/2003	Ashish Anilbhai Patel	G-33574P1	7968

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
OH, SIMON J	

ART UNIT	PAPER NUMBER
1618	

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/743,366	PATEL ET AL.	
	Examiner	Art Unit	
	Simon J. Oh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,9 and 11-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9 and 11-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's appeal brief and petition for extension of time, both received on 23 January 2006.

Withdrawal of Finality

The examiner withdraws the finality of the Office Action of 21 March 2005 and now re-opens prosecution on this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 23 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating specific diseases (e.g., narcolepsy, hypersomnia, depression and Alzheimer's disease), which can be treated by the administration of modafinil, does not reasonably provide enablement for treating any other disease or disorder as broadly claimed in Claim 23. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth hereinbelow.

1. The nature of the invention, state of the prior art, relative skill of those in the art, and the predictability of the art

The claimed invention relates to treating a disease or disorder in a subject in need thereof, which encompasses any disease and disorder. Various diseases having various different causes are not treatable by a single composition. Given the great diversity between various diseases (viral infections, bacterial infection, cancers, autoimmune diseases, clogged arteries, neurological diseases, etc.), the unpredictability of treating a subject (e.g., no specific disease) has a number of facets, as discussed hereinafter.

A. Treatment of Disease Type

While the state of the art is relatively high with regard to the treatment of specific diseases with a specific agent, it is long underdeveloped with regard to the treatment of a subject

broadly, that is, general treatment, with no specific disease combined with a specific drug therefore. In particular, there is no known "treatment" drug, that can treat, "all that ails you". This is why the National Cancer Institute (NCI) has the extensive *in vitro* drug-screening program it does. As discussed by the court in *In re Brana*, 51 F.3d 1560 (Fed. Cir. 1995), *in vitro* assays are used by NCI (such as the P388 and L1210 lymphocytic leukemia tests at issue therein) to measure the potential antitumor properties of a candidate compound. *Brana* at 1562-63. If success is shown in this initial screening step, this demonstrates that at least one cancer type (e.g., lymphocytic leukemia) is sensitive thereto, and provides the incentive to select it for further studies to determine its usefulness as a chemotherapeutic agent against other cancer types (lung, breast, colon, etc.) *Id.* at 1567-68. These *in vitro* tests are considered reasonably correlative of success *in vivo*.

Thus, a considerable amount of *in vitro* empirical testing is required, with no *a priori* expectation of success being present, before a candidate for even treating a specific disease, such as, cancer.

B. The therapeutic agent used

The claim is drawn to a method of treatment by the administration of a single drug, modafinil. Thus, surely there is no means of treating any disease by the administration of a single known drug.

2. The breadth of the claims

The claim is very broad and inclusive of "treating a disease or disorder in a subject in need thereof" generally, which includes any treatment. Clearly, the methods are only used to

treat diseases that are known to be treatable with the administration of modafinil, such as narcolepsy, hypersomnia, depression, Alzheimer's disease, stroke, eating disorders, and ADHD.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction for ascertaining, *a priori*, which diseases can be treated, except those that are known to be treatable with the administration of modafinil, such as narcolepsy, hypersomnia, depression, Alzheimer's disease, stroke, eating disorders, and ADHD.

4. The quantity of experimentation necessary

The lack of adequate guidance from the specification or prior art with regard to the actual treatment fails to rebut the presumption of unpredictability present in this art. Applicants fail to provide the guidance and information required to ascertain which particular disease the claimed method will be effective against without resorting to undue experimentation. Applicant's limited disclosure of the treatment of is not sufficient to justify claiming all treatment broadly.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-5, 7-9, and 11-23 under 35 U.S.C. 103(a) as being unpatentable over Corvari *et al.* in view of Bentolila *et al.* is hereby withdrawn.

Claims 1-5, 7, 9, and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Corvari *et al.* (U.S. Patent Application Publication No. 2003/0220403 A1) in view of Heacock *et al.* (U.S. Patent Application Publication No. 2004/0048931 A1)

The Corvari *et al.* publication discloses modafinil compositions formulated with various excipients (See Abstract). Various glidants may be used in the disclosed compositions, including calcium silicate and magnesium trisilicate (See Section 0026). Suitable diluents include lactose, starch, and microcrystalline cellulose (See Sections 0021 and 0022). Suitable disintegrants include pre-gelatinized starch and cross-linked sodium carboxymethylcellulose (See Section 0023). Suitable lubricants include magnesium stearate (See Section 0025). The composition may be formulated as either tablets or capsules (See Section 0047). Processes for making the compositions are disclosed, as well as methods of treatment (See Claims 16 and 52).

The Corvari *et al.* publication discusses particle size in only general terms (See Section 0051).

The Heacock *et al.* publication discloses pharmaceutical compositions comprising modafinil particles, wherein at least about 5% of the particles have a diameter greater than 200 microns (See Claims 1 and 3). The disclosed modafinil particles have particle sizes that are customized and controlled in order to achieve a desired potency and safety profile (See Abstract; and Sections 0006 and 0018).

It would be obvious to one of ordinary skill in the art to combine the two prior art references in order to obtain the instantly claimed invention. One of ordinary skill in the art would be motivated to incorporate the improvements presented in the Heacock *et al.* publication regarding particle sizes into other prior art references that disclose modafinil compositions such

as Corvari *et al.*, is order to obtain a modafinil composition with an improved potency and safety profile. As both references disclose oral modafinil compositions, they are analogous art and can thus be properly combined by one of ordinary skill in the art with a reasonable expectation of success. Thus, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 23 January 2006 have been fully considered but they are considered moot in view of the new grounds of rejection above.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh
Examiner
Art Unit 1618

sjo

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER